1.1 Fundamentals of Medical Instrumentation

The field of computers in medicine is quite broad. During the last quarter of the century, there has been a tremendous increase in the use of the electrical and electronic equipment in the medical field for clinical and research purposes. In a medical instrumentation system (MSI), the main function is to measure and determine the presence of some physical quantity that may be useful for diagnostic purposes. Therefore, many types of instrumentation systems are used in hospitals and physicians clinics. Knowledge of the structure of the living body and its function is essential for understanding the functioning of most of the medical instruments. The science of structure of the body is known as “ANATOMY” and that of its function is known as, “PHYSIOLOGY”. Figure 1.1 shows the three basics types of data that must be acquired, manipulated, and archived in the hospital. Alphanumeric data include the patient’s name and address, identification number, results of lab tests and physician’s notes. [89]
1.2 Overview of Medical Instruments

There are many different types of medical instruments. Our work is related and concentrated on monitoring and analyzing physiological signals from a patient using ECG.

Figure 1.2 shows block diagram that characterizes such instruments. Sensors measure the patient’s physiological signals and produce electrical signals that are analogs of the actual signals. A set of electrodes may be used to sense a potential difference on the body surface commonly used in ECG. The electrical signals produced by the sensors are interfaced to the processor which is responsible for processing and analysis of the signals. The processor block typically includes a microprocessor for performing the necessary tasks. Many instruments have the ability to display, record, or distribute through a network either the raw signals captured by the processor or the results of its analysis. In some instruments, processor performs a control function [90]. Based on the results of the signal analysis, the processor performs a control
function. Based on the results of the signal analysis, the processor might instruct a controller to do direct therapeutic intervention on a patient (Closed loop control) or it may signal a person that there is a problem that requires possible human intervention (open loop control).[2]
Human body is a complex engineering marvel, which contains various types of systems such as electrical, mechanical, hydraulic, pneumatic, chemical and thermal etc. These systems communicate internally with each other and also with an externally environment [49][53]. By means of a multi-level control system and communications network, the individual systems enable the human body to perform useful tasks, sustain life and reproduce itself.

1.3.1 The Cardiovascular System
The cardiovascular system is a complex closed hydraulic system, which performs the essential service of transportation of oxygen, carbon dioxide, numerous chemical compounds and the blood cells. Structurally, the heart is divided into right and left parts [53]. Each part has two chambers called atrium and ventricle. The heart has four valves (seen in figure 1.3): [90]

- **Tricuspid valve or right atrio-ventricular valve** – between right atrium and ventricle. It consists of three flaps or cusps. It prevents backward flow of blood from right ventricle to right atrium.
- **Bicuspid Mitral or left atrio-ventricular valve** – between left atrium and left ventricle. The valve has two flaps or cusps. It prevents backward flow of blood from right ventricle to atrium.
- **Pulmonary valve** – at the right ventricle. It consists of three half moon shaped cusps. This does not allow blood to come back to the right ventricle.
- **Aortic valve** - between left ventricle and aorta. Its construction is like pulmonary valve. This valve prevents the return of blood back to the ventricle from aorta.

The heart wall consists of three layers:

i) **The Pericardium**, which is the outer layer of the heart. It keeps the outer layer moist and avoids friction as the heart beats.

ii) **The Myocardium** is the middle layer of the heart. It is main muscle off the heart, which is made up of short cylindrical fibres. This muscle is automatic in action, contracting and relaxing rhythmically throughout life.
iii) The *Endocardium* is the inner layer of the heart which provides smooth lining for blood to flow.

The blood is carried to the various parts of the body through blood vessels, which are hollow tubes. There are three types of blood vessels;

i) *Arteries* are thick walled and they carry the oxygenated blood away from the heart.

ii) *Veins* are thin walled and carry de-oxygenated blood towards the heart.

iii) *Capillaries* are the smallest and last level of blood vessels. They are so small that the blood cells, which make blood, actually flow one at a time through them. There are estimated to be over 800,000 km of capillaries in human being, which include all the arteries and veins, which carry blood.

![Figure 1.3: Structure of the Heart](image)
1.4 Overview of Cardiovascular diseases

Cardiovascular disease (CVD) including heart diseases and strokes, accounts a major cause of morbidity and mortality in today’s world and will become the leading cause of death and disability worldwide by 2020. It is the leading cause of death in the USA with almost 2000 Americans dying each day, i.e. one death in every 43 seconds. Among the non communicable diseases, CVD are the leading cause of death responsible for 30% of all deaths (17.5 million people in 2005 worldwide). According the recent estimate cases of CVD may increase from 2.9 crores in 2004 to as many as 6.4 crores in 2015. Prevalence rate of CVD in rural population will continue to increase reaching around 13.5% in the age group of 60-69 years by 2015. The diseases constituting its range of fatal expression include heart attack, myocardial infarction, acute coronary syndrome, congestive failure, strokes, kidney disease and peripheral vascular disease occur when the blood flow is blocked owing to the presence of blood clot while strokes are the results of blocked or burst blood vessels in the brain. Congenital heart defects and a range of other condition which occur due to improper pumping of blood cause long term problems, and even deaths for sufferers.

1.5 Introduction to Electrocardiography

One of the main techniques for diagnosing heart disease is based on the electrocardiogram (ECG). The electrocardiograph or ECG machines permits deduction of many electrical and mechanical defects of the heart
by measuring ECGs, which are potentials measured on the body surface.

There are three basic techniques used in clinical electrocardiography. The most familiar is the standard clinical electrocardiogram. This is the test usually done at the physician’s office in which 12 different potential differences called ECG leads are recorded from the body surface of a resting patient.

A second approach uses another set of body surface potentials as an input to three dimensional vector model of cardiac excitation. This produces a graphical view of the excitation of the heart called the vectorcardiogram (VCG) [90]. Finally, for long term monitoring in the intensive care unit, one or two leads are monitored or recorded to look for life threatening disturbances in the rhythm of the heart beat. This approach is called, “ARRHYTHMIA ANALYSIS”.

Thus the basic three techniques used in electrocardiography are:

1) Standard Clinical ECG (12 leads)
2) VCG (3 orthogonal leads)
3) Monitoring ECG (1 or 2 leads)
Figure 1.5: Objective of the electrocardiography is to deduce the electrical & mechanical condition of the heart by making non-invasive body surface potential measurements.

Figure 1.5 shows the basic objective of electrocardiography. By looking at the electrical signals recorded only on the body surface, a completely non-invasive procedure, cardiologists attempt to determine the functional state of the heart [89]. Although ECG is an electrical signal, changes in the mechanical state of the heart lead to changes in how the electrical excitation spreads over the surface of the heart, thereby changing the body surface ECG. The study of cardiology is based on the recording of the ECGs of thousands of patients over many years and observing the relationships between various waveforms in the signal and different abnormalities. Thus clinical electrocardiography is largely empirical, based mostly on experiential knowledge.

1.6 Definition of ECG

An electrocardiogram (ECG or EKG, abbreviated from the German Electrocardiogram) is a graphical representation of potential difference on body surface, which records the electrical voltage in the heart in the form of a continuous strip graph. Working of the cardiac system can be judged from this ECG, representing the muscular contractions that the heart does
in-order to pump blood to the vascular system. In general, the electrocardiogram is a technique of recording bioelectric currents generated by the heart [7]. Clinicians can evaluate the conditions of a patient’s heart from the ECG and perform further diagnosis. ECG records are obtained by sampling the bioelectric currents sensed by several electrodes, known as leads.

1.6.1 Characteristics of ECG

![ECG diagram]

The normal electrocardiogram (ECG) is comprised of characteristic deflections referred to as P, Q, R, S, and T waves. The P wave is caused by the current generated just before the contraction of the atria. The complex QRS wave is the result of the currents generated in the ventricles during

Figure 1.6 Characteristics of ECG w.r.t. the anatomy of Heart

The normal electrocardiogram (ECG) is comprised of characteristic deflections referred to as P, Q, R, S, and T waves. The P wave is caused by the current generated just before the contraction of the atria. The complex QRS wave is the result of the currents generated in the ventricles during
depolarization just prior to ventricular contraction, the R wave being the dominant component [5].

Characteristic waveform of ECG is as follows:

![Figure 1.7 Components of ECG Waveform](image)

From figure above, we conclude that; [5]

a)  P wave - Marks the beginning of ECG wave
b)  PR segment - Measured from beginning of P wave to beginning of QRS complex
c)  QRS Complex - Complex formed out of Q, R & S wave with duration less than 0.12 sec
d)  Q-T interval - Measured from beginning of Q wave to end of T wave
e)  S-T interval - Interval between S wave & T wave
f)  T wave - Marks the end of ECG wave

The above shown deflections or nodes have specific amplitude and duration.
<table>
<thead>
<tr>
<th>Amplitude</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>P wave 0.25mv</td>
<td>P-R Interval 0.12 to 0.20 sec</td>
</tr>
<tr>
<td>Q wave 25% of R wave</td>
<td>Q-T Interval 0.35 to 0.44 sec</td>
</tr>
<tr>
<td>R wave 1.60mv</td>
<td>S-T 0.05 to 0.1 sec</td>
</tr>
<tr>
<td>T wave 0.1 to 0.5mv</td>
<td>P wave Interval 0.1 sec</td>
</tr>
<tr>
<td></td>
<td>QRS Interval 0.09 sec</td>
</tr>
</tbody>
</table>

Note: These measurements are as per the standard ECG Signal on an ECG sheet.

If these deflections and the interval between the points vary from standard values then we can comment that there is some disturbance in the patient’s rhythmic contractions. These disturbances are termed Cardiac arrhythmias. Cardiac arrhythmia is a group of conditions in which the muscle contraction of the heart is irregular or is faster or slower than normal. Some arrhythmias are life-threatening medical emergencies that can cause cardiac arrest and sudden death. Others cause aggravating symptoms, such as an awareness of a different heart beat, or palpitation, which can be annoying. Some are quite benign and normal [7].

1.6.2 Electrical Activity of Heart

The heart contains special group of cells called the ‘pacemaker cells’ which have the ability to generate electrical activities on their own. Electricity is produced when these cells change their electric charge from positive to negative and back. The first electric wave is initiated at the top
of the heart in a heart beat and due to the inherent property of the heart muscle cells to propagate electric charge to adjacent muscle cells; the initial electric wave is enough to trigger a chain reaction. Specialized fibers in the heart conduct the electrical impulse from the pacemaker to the rest of the heart.

The three important parts of the heart’s electrical activity are (refer figure 1.6 Characteristics of ECG w.r.t. the anatomy of Heart) [53]

1. The SA node (Sinoatrial node) – It is the heart’s natural pacemaker which initiates each heart beat
2. The AV node (Atrioventricular Node) - it acts as a bridge between Atria and the ventricles, allowing electrical signals from the atria into the ventricles.
3. His-Purkinje system- It carries the electrical signals throughout the ventricles and consist of the following essential parts:
   - His-bundle
   - Right Bundle branch
   - Left bundle branch
   - Purkinje fibers

**1.6.3 Blood Flow**

The heart is filled with blood when then these heart muscles relax in between heart beats and this process of relaxation is called diastole. Thus, it can be summarized that the right side of the heart collects the deoxygenated blood from the body and pumps it to the lungs for oxygenation and release of waste products like CO\textsubscript{2}. The left side of the
heart collects oxygenated blood from the lungs and pumps it to the body such that all the cells in the body receive the oxygen supply they require for proper functioning. [47]

1.6.4 Uses of ECG

The ECG has a wide array of uses such as:

- Determining the heart condition (normal or abnormal)
- It may indicate acute or previous damage to heart muscles or ischemia of heart muscle (angina)
- Detection of potassium, calcium, magnesium, and other electrolytes disturbances
- Detection of conduction abnormalities
- Used as screening tool for ischemic heart diseases during an exercise tolerance test
- Can provide information on physical conditions of the heart
- Can suggest non cardiac diseases

1.7 Cardiac Arrhythmia

Cardiac arrhythmia is a term that denotes disturbances of the heart rhythm. Cardiac arrhythmias can range in severity from entirely benign to immediately life threatening. If arrhythmia is suspected, a cardiologist should be consulted for confirmation. In addition, the use of natural substances for arrhythmia should always be supervised by a doctor. A cardiac Arrhythmia is also called as Dysrhythmia; disturbance in the regular rhythm of the heartbeat. [20]
Normally the heart contracts 60 to 100 times per minute with each contraction representing a heartbeat. Arrhythmias can occur when;

- The natural pacemaker develops an abnormal rate
- The normal flow of conduction is blocked
- Another part of the heart acts as the pacemaker

It could also be caused by stress, caffeine, tobacco, alcohol and cough and cold medicines. Some arrhythmias are life threatening medical emergency that can cause cardiac arrest and sudden death others cause aggravating symptoms, such as an awareness of a different heart beat, palpitation, which can be annoying. Some are quite benign and normal. Sinus arrhythmias are the mild acceleration followed by slowing of the normal rhythm that occurs while breathing. In adults the normal heart rate ranges from 60 to 100 bpm. The normal heart beat is controlled by a small area in the upper chamber of the heart called the sinoatrial node or sinus node. The sinus node contains specialized that have spontaneous electrical activity that starts each heart beat.

1.7.1 Types of Cardiac Arrhythmia

Few of the commonly seen arrhythmias are listed below; [72]

1) Supraventricular Tachycardia – Supraventricular tachycardia (SVT) is a series of very rapid heartbeats that begin in the heart’s upper chambers. Generally supraventricular tachycardia is not a life threatening problem although it can be quite bothersome and frightening. SVT may occur when an extra pathway exists in the atria, the AV node or between the atria and ventricles. An electrophysiology study can be used to identify the origination site of SVT.
2) Atrial Fibrillation – In patients with atrial fibrillation, multiple sites in the atria send electrical impulses in an uncoordinated fashion. As a result, the atria beat very quickly and ineffectively. The AV node, which acts as a relay station, allows only some of these impulses to travel down the electrical system and simulate the ventricles. As a result, the heart rhythm is irregular, erratic and usually rapid.

![Atrial Fibrillation ECG Waveform](image)

Figure 1.8: ECG Waveform – Atrial Fibrillation

3) Bradycardia: With a greater increase in the parasympathetic tone and a decrease in sympathetic stimulation, the normal sinus rhythm slows. Bradycardia is defined as slow heart rhythm. It is generally divided into 2 categories, sick sinus syndrome and heart block. These slow heart rhythms are usually treated by implantation of a permanent pacemaker, which takes over the work of the hearts normal pacemaker.

![Bradycardia ECG Waveform](image)

Figure 1.9: ECG waveform – Bradycardia

4) Wolff-Parkinson-White Syndrome (WPW) – An abnormal bridge of tissue connects the atria and ventricles. This extra pathway called
an accessory pathway makes it possible for electrical impulses to travel from the atria to the ventricles without going through the AV node. Patient with WPW syndrome experience arrhythmias when an impulse travels down the AV node to the ventricles, and then up through the necessary pathway to the atria. If the pulse continues to travel in the circular pattern, it may cause the heart to contract with each cycle. This could result in a very rapid heartbeat, which could allow extremely rapid and potentially serious rhythms to occur.

5) Tachycardia - A reduction of parasympathetic tone or an increase in sympathetic stimulation will raise the frequency of heartbeats. When conduction is normal and the rate is greater than 120bpm, then the rhythm is called sinus tachycardia.

Figure 1.10: ECG waveform - Tachycardia

6) Sinus Arrhythmia - This is characterized by variations in heart rate from beat to beat that are greater than would be expected from normal respiratory variation. It is irregular and caused by fluctuations of autonomic tone that result in physical changes of the discharge rate.
7) Bigeminy - (Latin: Bi-Two Gemini-twins) is a descriptor for a heart arrhythmia in which abnormal heart beats occur every other concurrent beat. A typical example is with bigeminal premature ventricular beats, also known as premature ventricular contractions/complexes (PVC). Following the PVC there is a pause and then the normal beat returns - only to be followed by PVC.

8) Ventricular Tachycardia - comes from the Greek words tachys (rapid or accelerated) and kardia (of the heart). Tachycardia typically refers to a heart rate that exceeds the normal range for a resting heart rate (heart rate in an inactive or sleeping individual). In humans, the upper threshold of a normal heart rate is usually based upon age, sometimes it can be very dangerous depending on how hard the heart is working and the activity.
9) Trigeminy - An arrhythmia in which 2 normal QRS complexes are followed by a PVC; this rhythm usually does not progress to dangerous forms of fast ventricular rhythms; in this rhythm, two VPCs never occur one right after the other 2.

1.7.2 Causes & Symptoms of Cardiac Arrhythmia

Cardiac arrhythmias occur when the heart beats improperly, as a result of incorrect impulse generation, or impulse conduction. The heart organ broadly differentiates into two types of cell, pacemaker cells, and non-pacemaker cells. Pacemaker cells beat with their own independent rhythm, in synchrony with their neighbors. The non pacemaker cells require stimulus to beat or contract, this stimulus comes from the pacemaker cells [72].
The symptoms of cardiac arrhythmia are not necessarily life threatening, unless left untreated, cardiac arrhythmia can lead to more fatal forms of rhythm disturbance, example: premature ventricular depolarization may lead to ventricular fibrillation resulting in heart attack. The signs and symptoms of cardiac arrhythmias range from completely asymptomatic to loss of consciousness or sudden death. In general, more severe symptoms are more likely to occur in the presence of structural heart disease. For example, sustained monomorphic VT, particularly in a normal heart, may be hemodynamically tolerated and causes marked symptoms in patients with severe LV dysfunction. Complaints such as lightheadedness, dizziness, quivering, shortness of breath, chest discomfort, heart fluttering or pounding and forcefully or painful extra beats are commonly reported with a variety of arrhythmias. Frequently patients notice their arrhythmia only after checking peripheral pulses.
1.8 Basics of Patient Monitoring System

The objective of the patient monitoring is to have a quantitative assessment of the important physiological variables of the patients during critical periods of their biological functions. For diagnostic and research purposes, it is necessary to know their actual value or trend of change. Patient monitoring systems are used for measuring continuously or at regular intervals, automatically, the values of the patient’s important physiological parameters. There are several categories of patients who may need continuous monitoring or intensive care. The long term objective of patient monitoring is generally to reduce mortality and morbidity by:

i) Organizing and displaying information in a form meaningful for improved patient care,

ii) Correlating multiple parameters for clear demonstration of clinical problems,

iii) Processing the data to set alarms on the development of abnormal conditions,

iv) Providing information, based on automated data, regarding therapy,

v) Ensuring better care with fewer staff members.

The choice of proper parameters, which have high information content, is an important issue in patient monitoring. It is, however, generally agreed that monitoring of the following biological function is often needed. Electrocardiogram (ECG), Heart Rate (Instantaneous or Average), pulse rate, blood pressure, body temperature and respiratory rate [37]. But the general requirements for patient monitoring equipments have not changed much over the last past few decades. However, today’s
equipment monitors more parameters and processes more information. Trends in monitoring include software control, arrhythmia monitoring, Haemodynamics monitoring, monitoring during transportation of the patient, and increased user friendly. With more than 10 parameters to measure and scores of calculations to be made, the requirement for easy to use user interface has assumed great significance.

1.8.1 Cardiac Monitoring

The most important physiological parameters monitored in the intensive care units are the heart rate and the morphology or shape of the electrical waveform produced by the heart. This is done to observe the presence of arrhythmias or to detect changes in the heart rate that might be indicative of a serious condition. Thus, a cardiac monitor is a specifically useful for monitoring patients with cardiac problems and the special areas in the hospitals where they are generally used are known as cardiac care units or coronary care unit (CCU). These instruments are also called ‘Cardio-sscopes’ and comprise of; [37]

i) Disposable type pre-gelled electrodes to pick up the ECG signal

ii) Amplifiers and a cathode ray tube for amplification and display of ECG which enable direct observation of the ECG waveform.

iii) A heart rate meter indicates average heart rate with audible beep or flashing light or both with each beat.

iv) An alarms system to produce signal in the event of abnormalities occurring in the heart rate.

Modern ECG monitors not only include the non fade display facility but also display heart rate along with the ECG trace.
1.8.2 Frequency response of Cardio-Scope

Some monitors have two selectable frequency response modes, namely Monitor and Diagnostic [29]. In the ‘Monitor’ mode or ‘Filter-in’ mode, both the low frequency and high frequency components of an ECG are attenuated. It is used to reduce baseline wander and high frequency noise. The monitor mode bandwidth is generally 0.4 to 50 Hz (3dB points). In the ‘Diagnostic’ mode, the instruments offers expanded bandwidth capability of 0.05 to 100Hz. Some instruments include a 50 Hz notch filter to improve the common mode rejection ratio and this factor should be kept in mind while checking the frequency response of the instrument. The patient circuit is isolated by using a transformer and by modulating the 102 kHz carrier signal with amplified and filtered ECG. The modulated carrier is demodulated in the cardio scope, amplified and applied to an analog-to-digital converter. The converter samples the waveform at a rate of 250samples/second, converts each sample to an 8-bit parallel word, and enters the word into the re-circulating memory where it replaces the oldest word stored. [12]
1.8.3 Proposed Patient Monitoring System

The proposed patient monitoring system performs following listed basic tasks:

i) **Detect ECG waveform using Embedded Controllers.**

ii) **Determine and display various deflections and nodes of the waveform after accurate processing.**

iii) **Determine heart rate and display it.**

iv) **Determine various intervals (RR interval, PR segment, QRS Complex interval)**

v) **Determine possible arrhythmia (cardiac disorder).**

vi) **Transmission of information to expert doctor available.**

The whole system works under the control of the processor LPC2103 which works at 32MHz. The processor board for following listed parameters is described in the subsequent sections;

1) Microprocessor board including analog signal multiplexer, A-D converter and real time clock (Motherboard + ECG card + Power supply card)

2) Video control board to convert the CPU commands into video signals (HMI)

3) Motherboard including signal buses and analog input signal buffers

4) Keyboard – Using standard keyboard as the system is connected to the computer
5) Software for calculation of heart rate, noise eradication, signal processing, arrhythmia detection, transmission of signal, gain adjustment, mode adjustment, and displaying of signal.